The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure

Board of Registration in Pharmacy
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LAUREN A. SMITH, MD, MPH
INTERIM COMMISSIONER

TO: All Pharmacies and Pharmacists

FROM: Madeleine Biondolillo, MD, Bureau Director

DATE: April 9, 2013

RE: Amendments to Regulations: 247 CMR Board of Registration in Pharmacy

BACKGROUND

In light of the recent tragic events involving certain compounding pharmacies operating in Massachusetts, on November 1, 2012, the Massachusetts Board of Registration in Pharmacy ("Board") approved emergency regulations to enhance the Department of Public Health's ("Department" or "DPH") oversight of this industry. The amendments became effective on November 1, 2012, and in response to public hearing comments were subsequently revised on January 8. These amendments will enable the Board to proactively and effectively monitor compounding pharmacy business practices, including for the first time the requirement for pharmacies to report both the volume and distribution of compounded products. This reporting will assist the Board in determining whether compounding pharmacies are operating in a traditional and necessary role rather than acting in a manner analogous to that of a manufacturing facility, subject to Food and Drug Administration licensing and regulatory oversight in conformance with current Good Manufacturing Practices.

WHAT IS NEW IN THESE REGULATIONS?

The amendments include new definitions, reporting requirements, and provisions for enhanced enforcement activities. The amendments may be found on the Board website at: http://www.mass.gov/eohhs/provider/licensing/occupational/pharmacy/

Definitions

New definitions in the amendments include:

- abnormal results
- accreditation
- disciplinary action
- federal agency
- state agency
- sterile compounding

Pursuant to these amendments,

Abnormal results means results of viable and nonviable testing, such as for environmental contaminants and potency, that are not within acceptable United States Pharmacopeia General Chapter 797 standards or criteria.

Accreditation means a process by which a professional association or non-governmental agency grants recognition to a pharmacy for demonstrated ability to meet certain pre-defined criteria.

Disciplinary actions means actions including, but not limited to revocation, suspension, probation, censure, reprimand, or restriction of the license to operate a pharmacy or practice pharmacy, denial of application for renewal, denial or restriction of privileges or termination from Medicare or Medicaid programs including any adverse actions or fines imposed by a state or federal agency.

Federal agency means any U.S. Government agency that has regulatory purview over the clinical practice of pharmacy or of pharmacy operations, including, but not limited to, all agencies in the U.S. Department of Health and Human Services, the U.S. Occupational Safety and Health Administration, and the U.S. Department of Justice.

State agency means any U.S. State or Territory that licenses or otherwise regulates pharmacies or pharmacist practice.

Sterile compounding means the preparation, mixing, assembling, packaging, and labeling of a drug or device that is required to be prepared in accordance with United States Pharmacopeia General Chapter 797 and dispensing pursuant to a valid prescription as defined by 247 CMR 2.00.

Reporting Requirements

The new regulations require pharmacies to report certain events and circumstances to the Board within specified timeframes. The new reporting requirements may be summarized as follows:

	Event / Circumstance to be Reported	**Deadline for Report**
247 CMR 6.15(2)	Non-routine notices, correspondence, and disciplinary actions	Within 7 business days of receipt
247 CMR 6.15(3)	Adverse change in status of accreditation, including but not limited to, withdrawal, discontinuance, termination, revocation, suspension, probation, or warning	Within 7 business days of an action taken by the accrediting agency
247 CMR 6.15(6)	Errors relating to preparation of medications in that pharmacy	Within 7 business days of identification of the error

	Event / Circumstance to be Reported	Deadline for Report
247 CMR 6.15(7)	Abnormal results, including failure of certification as required pursuant to 247 CMR 6.01(5)(c), and identification of environmental contaminants or improper potency in that pharmacy inconsistent with United States Pharmacopeia (USP) General Chapter 797 standards or criteria	Within 7 business days of abnormal results
247 CMR 10.03(1)(y)	Discipline (247 CMR 10.06) , on the basis of actions listed in 247 CMR 10.03(1)	7 days of the disciplinary action
247 CMR 10.03(1)(z)	Any final action~~,~~ (including license surrender or resignation)	7 days of the final action
247 CMR 10.03(1)(aa)	Any pending criminal charge or conviction	30 days of the charge or conviction

Until further notice, all reports should be submitted using the attached disclosure form to:

Board of Registration in Pharmacy
ATTN: Disclosure Reports
239 Causeway Street, 5th floor
Boston, MA 02114

Failure to comply with the reporting requirements or cooperate fully with the Board during any Board investigation of such reports will be grounds for disciplinary action by the Board.

Reporting by Sterile Compounding Pharmacies, as registered by the Board of Pharmacy (i.e., this does not include hospital pharmacies)

In addition, under the amendments to the regulations, pharmacies that perform central intravenous admixture services (CIVAS), or otherwise engage in sterile compounding, must report **every six months or upon request of the Board**, the following information:

- Total number of prescriptions dispensed, by USP General Chapter 797 risk-levels,
- Distribution data identifying the states in which the prescriptions were distributed, and status of any non-resident licenses issued by other states,
- Hood certifications required by 247 CMR 6.01(5)(c) ~~5~~4,
- All International Organization for Standardization (ISO) certifications in the ~~pharmacy~~ sterile compounding areas
- Status of CIVAS approval(s), where applicable, and
- Any other information required by the Board.

Initially, Sterile Compounding Pharmacies that perform CIVAS or otherwise engage in sterile compounding shall report this information on the attached form ("Sterile Compounding Reporting Form Nov-Dec 2012"), which includes an attestation of compliance with all laws and regulations related to sterile compounding. **The attestation shall be made under the pains and penalties of perjury and includes the following statement: "this registrant/licensee only prepares and dispenses medication pursuant to a valid prescription as defined in M.G.L.**

c.94C for a single patient, regardless of whether the medication is prepared for a Massachusetts or out-of-state patient."

In this first report, compounding pharmacies will provide a two-month 'snapshot' of information **for November and December, 2012** only. This report should be submitted to:

Board of Registration in Pharmacy
ATTN: Compounding Report
239 Causeway Street, 5th floor
Boston, MA 02114

The November/December report is due on or before Friday, April 26, 2013.

Be advised that all elements requested in this report should be tracked monthly going forward. The Board will distribute a similar reporting form for biannual reporting. The first report for the six month period January-June 2013 will be due on July 15, 2013. The report for the period July-December 2013 will be due on January 15, 2014.

The failure to comply with the reporting requirements will be grounds for disciplinary action by the Board. Questions related to the reporting requirements should be directed to: **pharmacy.admin@massmail.state.ma.us**

Board Approval for Initial Operation of Sterile Compounding (CIVAS)

Prior to initial operation of sterile compounding (CIVAS), pharmacies must obtain written approval from the Board indicating compliance with the requirements of 247 CMR 6.01 and United State Pharmacopeia General Chapter 797. Until further notice, such requests for approval should be sent to: **pharmacy.admin@massmail.state.ma.us**

The Board's notification of approval must be posted in a location visible to the public on the pharmacy premises.

Enforcement Actions

Finally, these regulations establish strict penalties for pharmacies and pharmacists concerning non-conformance with established federal and state laws and regulations related to compounding practices. These regulations also provide the Board with added authority to issue Summary Cease and Desist and Quarantine Notices when there is an immediate or serious threat to the public health, safety, or welfare.

Questions related to the new regulations or reporting requirements should be directed to: **pharmacy.admin@massmail.state.ma.us**

Attachment 1: Disclosure Reporting Form
Attachment 2: Sterile Compounding Reporting Form Nov-Dec 2012